

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte SREEKUMAR PILLAI, UMA SANTHANAM, MARIEANN
CARLOMUSTO, and CAROL ANNETTE BOSKO

Appeal No. 2001-1779
Application No. 09/398,898

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claim 2, the only pending claim. Claim 2 reads as follows:

2. A skin care composition comprising:
 - (i) an organic extract of chick peas in an amount such as to provide an estrogenic activity equivalent to at least 1 nM of estradiol;
 - (ii) a cosmetically acceptable vehicle.

The examiner relies on the following references:

Ohata et al (US '926)	4,333,926	Jun. 08, 1982
Kelly (WO '069)	WO 93/23069	Nov. 25, 1993

Claim 2 stands rejected as follows (Examiner's Answer, pages 3 and 4):

- (1) Under 35 U.S.C. § 102(b) as being anticipated by WO '069;
- (2) Under 35 U.S.C. § 102(b) as being anticipated by US '926; and
- (3) Under 35 U.S.C. § 103(a) as being unpatentable "over either WO '069 or US '926, each in view of the other."

We reverse all appealed rejections.

Discussion -- Anticipation

"Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all the elements of the claimed invention be described in a single reference." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990), citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). A reference which does not explicitly disclose a particular element of a claim may still be considered anticipatory if the reference inherently discloses that element. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950 (Fed. Cir. 1999). However, to establish that a particular element is inherently disclosed by a reference, the examiner must establish that the descriptive matter missing from the reference is necessarily present in the reference's disclosure, and that persons of ordinary skill would recognize the presence of that element. Id. at 745, 49 USPQ2d at 1950-51, citing Continental

Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

The examiner's rationale for rejecting claim 2 over WO '069 is set forth at page 3 of the Examiner's Answer as follows:

WO '069 discloses an isoflavone containing composition obtained by extraction of dried plant material with an aqueous:organic solvent extract (page 18, lines 4-8). The solvent may contain as much as 99.9% of the organic solvent. Chickpea as a suitable dried plant for extraction is disclosed at page 10, line 22. Topical products are disclosed at page 14, line 4.

The examiner has not established that WO '069 anticipates claim 2.

Claim 2 requires the extract to have "an estrogenic activity equivalent to at least 1 nM of estradiol." In the paragraph bridging pages 2 and 3, WO '069 discloses, that "oestradiol" is present in certain plants. However, the examiner's statement of rejection with respect to WO '069 fails to address the limitation in claim 2 requiring the extract to have "an estrogenic activity equivalent to at least 1 nM of estradiol."

To rebut appellants' argument in this regard (see Appeal Brief, page 10), the examiner states on page 5 of the Examiner's Answer:

[A]ppellants disclose at Table 1 that the amount of organic chickpea extract that provides estrogenic activity at least equivalent to 1 nM of estradiol is *at least* 0.1 µg/ml (emphasis added). WO '069 is directed to providing estrogenic activity by administering phyto-estrogens extracted from plants such as chickpea. WO '069 teaches amounts of organic solvent plant extract in much larger quantities than instantly disclosed. For example, see claim 7 for 20 to 200 mg per dosage unit. The compositions of WO '069 inherently have estrogenic activity at least equivalent to 1 nM of estradiol. There is no data or evidence of record that WO '069

does not provide the amount of estrogenic activity as instantly claimed.

We do not find the examiner's argument persuasive. On the current record we do not find, and the examiner does not point to, any facts or evidence establishing that any chickpea extract disclosed by WO '069 necessarily has the claimed estrogenic activity equivalent to a concentration of at least 1 nM estradiol. The data provided in appellants' specification at Table 1 (specification, page 15) demonstrate the estrogenic activity of the particular extract assayed therein. The data in Table 1 do not demonstrate that every organic extract of chickpea will have an estrogenic activity equivalent to at least 1 nM of estradiol.

Moreover, WO '069 does not disclose any examples wherein an organic extract of chickpea is prepared. Thus, WO '069 does not provide factual evidence, such as starting amounts of chickpea or chickpea extract, or amounts of extraction solvent, which can be used to establish that any chickpea extract disclosed by WO '069 necessarily has the claimed estrogenic activity. Because we do not discern facts in WO '069 allowing for a meaningful comparison between claim 2 and WO '069, we find that the examiner has not established that WO '069 inherently discloses an organic chickpea extract having an estrogenic activity equivalent to 1 nM of estradiol.

Inherency cannot be established by probabilities or possibilities, and the fact that a specific result might occur from a certain set of circumstances is insufficient to establish inherency. Robertson, 169 F.3d at 745, 49 USPQ2d at 1951, citing Continental Can, 948 F.2d at 1269, 20 U.S.P.Q.2d at 1749, citing

In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Moreover, because the examiner did not establish that WO '069 inherently discloses the claimed estrogenic activity, appellants need not provide evidence demonstrating a difference between the prior art and the claims. See Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658, citing In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986), and In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971) (applicant has burden of demonstrating difference between claimed product and prior art product when PTO provides sound basis for belief that the products are the same.). We therefore reverse the anticipation rejection of claim 2 over WO '069.

For similar reasons, we find that the examiner has not established that US '926 anticipates claim 2. The rationale for the examiner's holding of anticipation is set forth at page 4 of the Examiner's Answer as follows:

US '926 discloses a composition obtained from the extraction of chickpeas with an organic solvent such as hexane, methanol, or acetone (col. 1, lines 40-59). The extracts may be administered topically (col. 8, lines 23-26). US '926 teaches that it is within the skill of the art to calculate the effective amount of active material needed to achieve a therapeutic effect (col. 8, lines 35-38).

Again, however, the examiner fails to address why any chickpea extract disclosed by US '926 necessarily has the claimed estrogenic activity. In response to appellants' argument in this regard (see Appeal Brief, paragraph spanning pages 10 and 11), the examiner states at page 5 of the Examiner's Answer:

US '926 teaches an organic extract of chickpea. US '926 further teaches at column 8, lines 35 to 38 that the quantity of active material is that which will produce the desired therapeutic effect. There is no data or evidence of record that the chickpea extracts of US '926 do not provide the amount of estrogenic activity as instantly claimed.

We note, as pointed out by the examiner, that US '926 discloses at column 1, lines 50-59 that "Cicer arietinum" (chickpea) can be extracted in hexane, methanol, or acetone as an initial step in obtaining the steryl- β -D-glucosides which are the ultimate object of the extraction procedure disclosed by US '926. However, the examiner does not point to any facts or evidence which establish that such an extract will necessarily have an estrogenic activity equivalent to the claimed concentration of estradiol. Like WO '069, US '926 does not disclose any examples wherein an organic extract of chickpea is actually prepared. US '926 therefore does not provide factual evidence, such as starting amounts of chickpea or chickpea extract, or amounts of extraction solvent, which establish that any chickpea extract disclosed by US '926 will necessarily have the claimed estrogenic activity.

We note further, as pointed out by the examiner, that US '926 discloses at column 8, lines 35-38 that the quantity of active material is the amount calculated to produce a therapeutic effect. However, the active ingredients of US '926 are "steryl- β -D-glucosides" having hemostatic, vascular stabilizing and antishock therapeutic activities. US '926 at column 1, lines 12-56. Thus, even if US '926 is considered to disclose organic chickpea extracts having therapeutic properties, it is not clear that a therapeutic extract prepared according to US '926 will

necessarily have the required estrogenic activity. Anticipation is not established by picking and choosing isolated elements from unrelated portions of a reference and combining them to arrive at the claimed invention. See In re Arkley, 455 F.2d 586, 587-588, 172 USPQ 524, 526 (CCPA 1972). We reverse the anticipation rejection of claim 2 over US '926.

Discussion – Obviousness

Claim 2 stands rejected by the examiner under 35 U.S.C. § 103(a) as being unpatentable “over either WO ‘069 or US ‘926, each in view of the other.” Examiner’s Answer, page 4. The examiner’s rationale for holding claim 2 obvious is set forth at page 4 of the Examiner’s Answer as follows:

WO ‘069 and US ‘926 teach all of the limitations of the claim as stated above. Neither reference specifically teaches the amount of extract needed to achieve estrogenic activity at least equivalent to 1 nM of estradiol. It is within the skill of the art to determine the amount of active agent needed to achieve a beneficial and/or therapeutic effect. Therefore, absent evidence of unexpected results, no patentable weight is given to the claimed amount of chickpea extract. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of WO ‘069 and US ‘926 with the reasonable expectation of producing a topical composition that exhibits estrogenic activity.

We do not find the examiner’s reasoning persuasive of obviousness. The criteria for obviousness determinations are set forth in Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) as follows:

[T]he scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is

determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. (Citation omitted.)

“[T]o establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.” In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000), citing In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) and In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). One cannot establish motivation for combining references through unsupported conclusory statements. In re Lee, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002).

From the outset, the examiner’s rationale for holding claim 2 obvious over the cited references is unclear. The examiner states initially that “WO ‘069 and US ‘926 teach all of the limitations of the claim.” Examiner’s Answer, page 4. In view of this statement, it is unclear what the examiner considers to be the differences between the claim and the prior art, and how the prior art should be modified so as to meet the limitations present in the claim, as required by John Deere, supra.

While the examiner asserts that “[i]t is within the skill of the art to determine the amount of active agent needed to achieve a beneficial and/or therapeutic effect” (Examiner’s Answer, page 4), the examiner does not provide

any analysis regarding how the references should be modified to arrive at the claimed invention. Rather, the examiner provides the conclusory statement that “[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of WO ‘069 and US ‘926 with the reasonable expectation of producing a topical composition that exhibits estrogenic activity.” Examiner’s Answer, page 4. In contravention of Lee, supra, the examiner does not support this statement with any factual details explaining why one of ordinary skill would have been motivated to have combined the teachings of the cited references, or how, specifically, the references should be modified so as to result in the claimed subject matter.

In sum, because the examiner does not, with any degree of specificity, point to the relevant portions of the cited references which would have led the artisan of ordinary skill to a prepare a skin care composition having the claimed ingredients in the claimed amounts, we find that the examiner has not established a prima facie case of obviousness. We therefore reverse the appealed obviousness rejection.

Additional Issues

Our review of the record in this appeal included a review of parent application 08/901,052, which issued as U.S. Pat. No. 6,030,620 on February 29, 2002. We note that each of the patented claims recites a method of using the exact composition recited in appealed claim 2. Therefore, upon taking this case

up for action, the examiner should consider whether claim 2 should be rejected under the judicially created doctrine of obviousness-type double patenting over the claims of the patented parent case.

REVERSED

WILLIAM F. SMITH)	
Administrative Patent Judge)	
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)	
)	BOARD OF PATENT
TONI SCHEINER)	
Administrative Patent Judge)	APPEALS AND
)	
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